

REMARKS

Claims 1-30 are pending. Claims 10-17 have been amended to more accurately reflect the claimed invention. Claim 30 is new. Support for the amendment of claims 10-17 can be found in the original claims and paragraph [0047] of the specification. Support for claim 30 can be found in paragraph [0056] of the specification. No new matter has been added.

Examined claims 1-17 and 30 considered together with the following remarks are believed sufficient to place the application into condition for allowance. Accordingly, an early and favorable action on the merits is earnestly solicited at present.

Election/Restriction

The present action makes final the previous restriction requirement and withdraws claims 1-9 and 18-29 as being patentably distinct from claims 10-17 and/or require serious burden to search and examine those claims. Additionally, with regards to the species election, Applicants contend that once the elected species is found allowable, the Examiner is requested to expand the examination of the claims to the non-elected species. Applicants renew its traversal on the arguments previously presented. Nevertheless, in order to further the prosecution of this application, and without acquiescing to the Examiner's withdrawal of the claims while reserving the right to prosecute the original claims in the future, Applicants have withdrawn claims 1-9 and 18-29. Applicants preserve the right of petition from this requirement for restriction under 37 C.F.R. §1.144.

Rejection under 35 U.S.C. §112, Second Paragraph & 35 U.S.C. §101

Claims 10-17 stand rejected under 35 U.S.C. §112, Second Paragraph & 35 U.S.C. §101 for being confusing under 35 U.S.C. §112, Second Paragraph by reciting the use of the transplant without setting forth any steps, resulting in improper claims under 35 U.S.C. §101.

Reconsideration and withdrawal of the above rejections are respectfully requested based on the following considerations.

Claims 10-17 have been amended to recite critical elements in the composition of the periodontal transplant and removing the use statements from the claims, satisfying the requirements under 35 U.S.C. §112, Second Paragraph & 35 U.S.C. §101.

Rejection under 35 U.S.C. § 102

The Examiner rejects claims 10-16 under 35 U.S.C. § 102(b) as anticipated by Elia '503 (U.S. Patent 5,372,503).

Reconsideration and withdrawal of the above rejections are respectfully requested based on the following considerations.

Legal Standard For Anticipation

The standard for a rejection under 35 U.S.C. § 102(b) is established in MPEP §2131. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. If an independent claim is allowable under 35 U.S.C. § 102, then any claim depending therefrom is also allowable.

The Present Invention

The presently claimed invention is drawn to a periodontal transplant. The periodontal transplant contains:

- 1) A therapeutically effective amount of a tissue regenerating neurotrophic factor composition. In the specification at paragraphs [0008] through [0019], it is disclosed that the therapeutically effective amount, wherein it regenerates cementum, periodontal ligament, alveolar bone, dental pulp, enhances the production of repaired dentin in the pulp cavity, and prevents the apical invasion of gingival epithelium along the dental root surface.

2) A periodontally acceptable scaffold material. In the specification at paragraph [0047], it is disclosed that the scaffold is required (e.g. a missing site of the alveolar bone).

Distinctions Over the Cited Art

Elia ('503) U.S. 5,372,503

In contrast to the present invention, Elia '503 discloses at column 2, lines 18-41, a dental implant inserted in the alveolar bone, which is less likely to loosen after insertion. (*See below*)

Therefore, it is a principal object of the invention to provide an improved dental implant method and apparatus.

Another object of the invention is to provide an improved dental implant which can be inserted in an opening in the alveolar bone without requiring that the opening must, within close tolerances, have a specific shape and dimension.

A further object of the invention is to provide an improved dental implant which permits ready adjustment of the position of the implant after the implant is placed in an opening formed in the jawbone.

Still another object of the invention is to provide a dental implant method which permits an implant to be attached to alveolar bone housing a nerve.

Yet a further object of the invention is to provide a dental implant method which allows an implant to be utilized on alveolar bone which has experienced significant loss and recession of its mass.

Another and further object of the instant invention is to provide an improved dental implant which is less likely to loosen after insertion in the alveolar bone.
(Elia '503, column 2, lines 18-41; emphasis added)

In contrast to the Elia '503 disclosure, the present invention is drawn to a periodontal transplant comprising therapeutically effective amount of a tissue regenerating neurotrophic factor composition. Elia '503 does not disclose a transplant containing a tissue regenerating neurotrophic factor composition as claimed. Elia '503 merely discloses a dental implant, whereas the present invention is drawn to a periodontal transplant. A transplant is defined in the

art as a composition having the ability to transfer tissue from one part to another. In contrast, a implant is defined in the art as securing or inserting into living tissue.

Accordingly, the present invention is not anticipated by Elia '503 of record. Any contention of the USPTO to the contrary must be reconsidered at present.

Rejection Under 35 U.S.C. § 103(a)

Claim 17 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Elia '503 (U.S. Patent 5,372,503), as applied to claims 10-16 above, further in view of Dunn *et al.* '647 (U.S. Patent 5,707,647).

Reconsideration and withdrawal of the above rejections are respectfully requested based on the following considerations.

Legal Standard for Determining Prima Facie Obviousness

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however

without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper).

“In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification.” *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. “The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

The Supreme Court of the United States recently held that the teaching, suggestion, motivation test is a valid test for obviousness, but one which cannot be too rigidly applied. See *KSR Int'l Co. v Teleflex Inc.*, 127 SCt 1727, 82 USPQ2d 1385 (U.S. 2007). The Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, *ibid*, reaffirmed the Graham factors in the determination of obviousness under 35 U.S.C. § 103(a). The four factual inquiries under Graham are:

- (a) determining the scope and contents of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating evidence of secondary consideration.

Graham v. John Deere, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (U.S. 1966).

The Court in *KSR Int'l Co. v. Teleflex, Inc.*, *supra*, did not totally reject the use of "teaching, suggestion, or motivation" as a factor in the obviousness analysis. Rather, the Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious under 35 U.S.C. § 103(a).

Even so, the Court in *KSR Int'l Co. v. Teleflex, Inc.*, *ibid*, rejected a rigid application of the "teaching, suggestion, or motivation" (TSM) test, which required a showing of some teaching, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the prior art elements in the manner claimed in the application or patent before holding the claimed subject matter to be obvious.

Accordingly, while the courts have adopted a more flexible teaching, suggestion, motivation (TSM) test in connection with the obviousness standard based on the *KSR v. Teleflex* case, which case involved a mechanical device in a relatively predictable technological area, it remains true that, despite this altered standard, the courts recognize inventors face additional barriers in relatively unpredictable technological areas as noted in *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 83 USPQ2d 1169 (Fed. Cir. 2007).

Further, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336, quoted with approval in *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007).

Distinctions Over the Cited Art

Applicants contend that the arguments described above with respect to distinctions over the Elia '503 reference is equally applicable here (and are incorporated herein by reference in their entirety).

Additionally, the shortcomings of Elia '503 are not compensated by the disclosure of Dunn *et al.* '030. The Dunn *et al.* '030 reference is also limited to a surgically implantable device. In contrast, the present invention regenerates the periodontal tissue, in particular, the cementum, periodontal ligament, alveolar bone, or dental pulp. The medicament preferably prevents the apical invasion of gingival epithelium along the dental root surface, as disclosed in paragraph [0032]. These properties are distinct, and not disclosed in either of the references of Elia '503 or Dunn *et al.* '030.

As stated above, Elia '503 does not disclose a periodontal transplant. Dunn *et al.* '030 recites BDNF as a nerve growth promoting substance or recites periodontal ligament cell growth factor as a tissue growth promoting substance, both of which may be incorporated into a coating of an implantable medical device, and this citation does not provide any information on how a neurotrophic factor (such as BDNF) behaves in the periodontal tissue. Even if the two citations are combined, one skilled in the art could not obtain from such a combination any motivation to arrive at periodontal transplantation comprising a neurotrophic factor.

Further, the technical effect of the presently claimed periodontal transplant is unpredictable from the citations.

A dental artificial implant, such as the one disclosed in Elia '503 is capable of merely providing osseous integration to anchor the implant to the bone. Because a dental implant causes osseous tissues to directly attach or ankylose with the metallic fixture of the implant, it can eventually cause a loss of bone mass.

In contrast, the presently claimed periodontal transplant is capable of stimulating regeneration of periodontal tissues including both soft and hard tissues such as the periodontal ligament, cementum and alveolar bone, leading to establishment of integration between the periodontal tissues. This is supported by Example 2 in the specification.

Accordingly, the present invention is *not* rendered obvious in view of the teachings and disclosures of the cited references. Any contentions of the USPTO to the contrary must be reconsidered at present.

CONCLUSION

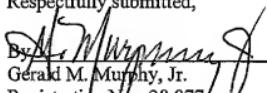
Reconsideration and withdrawal of the outstanding rejections of claims 10-17 are respectfully requested, inasmuch as the same are fully acceptable and patentable under provisions of Title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.147; particularly, extension of time fees.

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Respectfully submitted,

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